

Remarks

Claims 1 and 12 were amended to specify that the oil phase of the emulsion is a solid or semi-solid at room temperature. Support for the amendment is found at least at page 6, lines 26 to 27 and the examples.

Rejection Under 35 U.S.C. § 112, second paragraph

Claim 12 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner alleges that the term “predominantly” in claim 12 is a relative term which renders the claim indefinite. Without making any admissions and solely for the purpose of facilitating prosecution, claim 12 has been amended to delete the term “predominantly”.

Rejection Under 35 U.S.C. § 102

Claims 1 and 3-13 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2006/0140984 to Tamarkin *et al.* (“Tamarkin 1”). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986); *Scripps Clinic & Research Found v. Genentech Inc.*, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 U.S.P. Q.2d at 1010:

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Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. [...] There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in *Scripps*:

[A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

Id.

For a prior art reference to anticipate a claim, it must enable a person of ordinary skill in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it [...]" [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Paperless Accounting Inc. v. Bay Area Rapid Transit Sys.*, 231 U.S.P.Q. 649, 653 (Fed. Cir. 1986).

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Analysis

Claims 1 and 12 were amended to specify that the oil phase of the emulsion is a solid or semi-solid at room temperature..

Tamarkin 1

Tamarkin 1 describes an alcohol free cosmetic or pharmaceutical foam carrier containing water, a hydrophobic solvent, a foam adjuvant agent, a surface active agent, and a water gelling agent (abstract). The oil phase in the emulsion is a “hydrophobic solvent”. A “hydrophobic solvent” is defined as a liquid material having solubility in distilled water at ambient temperature of less than about 1.0 gm/100 mL, more preferably less than about 0.5 gm/100 mL, most preferably less than about 0.1 gm/100 mL (page 4, paragraph 0070). *The hydrophobic solvent is a liquid at room temperature* (page 4, paragraph 0070). In contrast, the independent claims require that the oil phase of the emulsion is a solid or semi-solid at room temperature. Tamarkin 1 does not disclose each and every element of the claims. Accordingly, claims 1 and 3-13, as amended, are novel over Tamarkin 1.

Rejection Under 35 U.S.C. § 103

Claims 1 and 3-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2006/0233721 to Tamarkin *et al.* (“Tamarkin 2”). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

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Legal Standard

Obviousness is a legal conclusion based on underlying facts of four general types, all of which must be considered by the examiner: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness. See *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459 (1966). This standard was recently affirmed by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). The Court did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

The Supreme Court did not obviate the requirement for the references to provide some motivation to combine as applicants have done, with a reasonable expectation of success. Indeed, the examiner's attention is drawn to the following quote by the Court in *KSR*:

"The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions

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usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. . . . There is no necessary inconsistency between the test and the *Graham* analysis.”

"Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness." *Gillette Co. v. S.C. Johnson & Sons, Inc.*, 919 F.2d 720, 724, 16 U.S.P.Q.2d 1923 (Fed. Cir. 1990); see *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 U.S.P.Q. 81, 93 (Fed. Cir. 1986). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures on the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

Analysis

Claims 1 and 12 were amended to specify that the oil phase of the emulsion is a solid or semi-solid at room temperature.

1. Tamarkin 2

As discussed above, the United States Supreme Court in *KSR* reaffirmed the *Graham* factors an obviousness analysis. The *Graham* factors are analyzed below:

(a) Determining the scope and contents of the prior art

The scope and contents of the prior art must be made *at the time the invention was made*. The requirement “at the time the invention was made” is to avoid impermissible hindsight. “It is difficult but necessary that the decision maker forget what he or she has been taught [...] about

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the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983).

Tamarkin 2

Tamarkin 2 describes a foamable composition containing a oil-in-water emulsion containing an oil globule system selected from the group consisting of oil bodies and submicron oil globules; 0.01% to about 5% by weight of agent selected from a non-ionic surface active agents having a HLB value between 9 and 16; an ionic surfactant, and a polymeric agent, and a liquefied or compressed gas propellant at a concentration of about 3% to about 25% by weight of the total composition (page 1, paragraph 0012). Oil bodies, also termed “oleosomes”, “lipid bodies”, and “spherosomes” are small discrete oleaginous particles, ranging in size from 1 to about 3 microns along one dimension, which consist of triacylglycerols (TAG) surrounded by phospholipids and alkaline proteins (page 3, paragraph 0038). Submicron oil globules are oil globules having a number average size of less than 1,000 nm.

The compositions contain a “hydrophobic organic carrier”. A “hydrophobic organic carrier” is defined as material having solubility in distilled water at ambient temperature of less than about 1.0 gm/100 mL, more preferably less than about 0.5 gm/100 mL, most preferably less than about 0.1 gm/100 mL (page 4, paragraph 0054). Suitable materials include oils, such as

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mineral oil; oils derived from vegetable, marine, or animal sources; essential oils; and silicone oils. These materials are liquids at room temperature.

(b) Ascertaining the differences between the prior art and the claims

In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 U.S. P.Q. 698 (Fed. Cir. 1983).

The Claimed Compositions and Methods

The claims define a topical aerosol foam containing:

(a) an active agent or agents selected from the group consisting of anti-inflammatory agents, topical anesthetics, topical antibiotics, anti-fungal agents, and combinations thereof, solubilized or dispersed in an oil and water emulsion, wherein the emulsion does not contain volatile lower alcohols, and wherein the oil phase of the emulsion is solid or semi-solid at room temperature; and

(b) a propellant consisting essentially of a hydrofluoroalkane or a mixture of hydrofluoroalkanes, without additional co-solvents or co-propellants, contacting the emulsion to produce an immediate foaming action on expulsion from a pressurized container.

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The foam is prepared an oil-in-water emulsion. The oil phase is a solid or semi-solid at room temperature. The oil phase does not contain oil bodies or submicron oil globules as required by Tamarkin 2.

Tamarkin does not disclose or suggest that the oil phase of the emulsion is a solid or semisolid at room temperature.

As discussed above, the composition described in Tamarkin 2 contain a “hydrophobic organic carrier”. These materials are liquids at room temperature, not solids or semi-solids as required by the claims. In fact, Tamarkin 2 teaches away from the claimed compositions and methods by stating that “[I]n one or more embodiments, the term “hydrophobic organic carrier” does not include thick or semi-solid materials, such as white petrolatum, which is disadvantageous due to its waxy nature and semi-solid texture” (pages 4 to 5, paragraph 0055).

It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. See *United States v. Adams*, 383 U.S. 39, 52, 148 U.S.P.Q. (BNA) 479, 484, 15 L. Ed. 2d 572, 86 S. Ct. 708 (1966) (“known disadvantages in

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old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness"); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550-51, 220 U.S.P.Q. (BNA) 303, 311 (Fed. Cir. 1983) (the totality of a reference's teachings must be considered), cert. denied, 469 U.S. 851 (1984); *In re Caldwell*, 50 C.C.P.A. 1464, 319 F.2d 254, 256, 138 U.S.P.Q. (BNA) 243, 245 (CCPA 1963) (reference teaches away if it leaves the impression that the product would not have the property sought by the applicant). One of ordinary skill in the art, reading Tamarkin 2, would not prepare an emulsion, wherein the oil phase is a solid or semi-solid at room temperature. Accordingly, one of ordinary skill in the art would not be motivated to modify the teachings of Tamarkin 2 to arrive at the claimed compositions and methods. Therefore, claims 1 and 3-13, as amended, are not obvious over Tamarkin 2.

The claimed compositions do not contain oil bodies or submicron oil globules as defined in Tamarkin 2

The compositions disclosed in Tamarkin 2 require oil bodies or submicron oil globules (i.e., a submicron emulsion). Oil bodies, also termed "oleosomes", "lipid bodies", and "sphaerosomes" are small discrete oleaginous particles, ranging in size from 1 to about 3 microns along one dimension, which consist of triacylglycerols (TAG) surrounded by phospholipids and alkaline proteins (page 3, paragraph 0038). Submicron oil globules are oil globules having a number average size of less than 1,000 nm. In contrast, the claimed compositions do not contain

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oil bodies or submicron oil globules as required by Tamarkin 2. Accordingly, claims 1 and 3-13, as amended, are not obvious over Tamarkin 2.

Double Patenting Rejection

Claims 1 and 9-11 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, and 17-19 of copending U.S.S.N. 11/128,947. Claims 1 and 9-13 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 9-16 of copending U.S.S.N. 11/464,100. Claims 1 and 3-13 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 9-16 of U.S.S.N. 11/552,457.

Applicants defer responding to these rejections until the claims are in condition for allowance.

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Allowance of claims 1 and 3-13, as amended, is respectfully solicited.

Respectfully submitted,

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